REMARKS

Claim Objections

The Examiner has objected to claims 1, 21 and 22 because the term "though" seems inappropriate to the Examiner. The Examiner is correct in assuming that this was a typographical error. Accordingly, Applicants have amended claims 1, 21 and 22 to change the word "though" to "through." Accordingly, this objection may now be withdrawn.

Claim Rejections

The Examiner has rejected claims 1, 4-9, 11, 16, 22, 25-30, 32 and 37 as being anticipated under 35 U.S.C. § 102(b) by Stephens (U.S. Patent No. 6,224,586). The Examiner has also rejected claims 1-9, 11-17, 19-30, 32-38 and 40-41 as being unpatentable under 35 U.S.C. § 103(a) over Figures 1-8 of Applicants' specification in view of Stephens. The Examiner has also rejected claims 10, 18, 31 and 39 as being unpatentable under 35 U.S.C. § 103(a) over Stephens.

Applicants have carefully considered the Examiner's comments. In order to put the claims in condition for allowance, Applicants have amended claims 1, 3, 12, 14, 17, 19-22, 33 and 38 and have cancelled claim 23. Applicants respectfully submit that the prior art of record does not disclose the limitations of Applicants' claims as now presented. Moreover, there is no proper motivation or suggestion to achieve the claimed invention by modifying or combining the prior art of record. In support of Applicants' position that the claims are patentable, Applicants submit herewith the declaration of Darin G. Schaeffer. In Mr. Schaeffer's declaration, he explains the differences between the claimed invention and Stephens and Figures 1-8 of the specification. Mr. Schaeffer also explains why it would not have been obvious to modify the prior art to achieve Applicants' invention. Applicants respectfully request due consideration of Mr. Schaeffer's declaration as well as the comments below.

Stephens does not anticipate the claimed invention because Stephens does not disclose an introducer with a beveled distal end or a flanged proximal end. As explained in Mr. Schaeffer's declaration, the device disclosed in Stephens is a position guide 100 for use with a pullback device 310. (Schaeffer ¶ 4). The Stephens position

guide 100 is not an introducer for introducing medical devices through a valve. (Schaeffer ¶ 4). Instead, the Stephens position guide 100 maintains a fixed distance between a Tuohy-Borst connector 308 and the pullback device 310. (Stephens at col. 3, lines 43-49). Because the Stephens position guide 100 is not an introducer, it does not have a beveled distal end or a flanged proximal end as recited in Applicants' claims. Therefore, Stephens cannot anticipate Applicants' claims under 35 U.S.C. § 102(b) because Stephens fails to disclose all of the limitations of Applicants' claims as presented.

The prior art of record also does not render the claimed invention obvious under 35 U.S.C. § 103(a). In Mr. Shaeffer's declaration, he explains that the Tuohy-Borst connector 308 disclosed in Stephens is not the hemastatic valve described in the present application. (Schaeffer ¶ 5). A Tuohy-Borst connector is a manually actuated connector that can be opened and closed by twisting the connector or by other manually actuated means. (Schaeffer ¶ 5). In order words, the user of the Tuohy-Borst connector can manually select whether the connector is open or closed, irrespective of whether a device is inserted through the connector. (Schaeffer ¶ 5). Typically, a Tuohy-Borst connector is operated by first manually opening the connector. (Schaeffer ¶ 5). A device is then inserted through the connector while it is open. (Schaeffer ¶ 5). The Tuohy-Borst connector is then manually closed to seal the connector against the inserted device. (Schaeffer ¶ 5).

By contrast, the hemastatic valve described in the application cannot be manually opened and closed by actuating the valve. (Schaeffer ¶ 3). The hemastatic valve used in the application is a specific type of valve that has a soft valve member and an opening extending through the valve member. (Schaeffer ¶ 3; Specification ¶ [0006]). The soft valve member is designed to collapse the valve opening so that the valve opening spontaneously closes when there is no device inserted through the hemastatic valve. (Schaeffer ¶ 3). In order to insert a device through the hemastatic valve, the device must be forced through the valve opening in the valve member. (Schaeffer ¶ 3; Specification ¶ [0006], [0015]). This causes the soft valve member to compress or flex sufficiently for the valve opening to expand to receive the device that is being inserted through the hemastatic valve. (Schaeffer ¶ 3; Specification ¶ [0006],

[0015]). As the device is inserted through the hemastatic valve, the valve member presses against the surfaces of the device to prevent blood from leaking through the valve opening. (Schaeffer ¶ 3; Specification ¶ [0006], [0015]). Thus, the hemastatic valve is naturally closed, and there is no actuation mechanism for opening the valve.

Because the position guide 100 disclosed in Stephens is not an introducer, there would have been no motivation to modify Stephens to achieve Applicants' invention. For example, because the Stephens position guide 100 is not forced through a hemastatic valve, there would have been no motivation to modify the distal end of the position guide 100 to add a beveled distal end. (Schaeffer ¶ 6). Furthermore, because the Stephens position guide 100 is not used to introduce medical devices, there would have been no motivation to add a flange at the proximal end to provide a funnel guideway. (Schaeffer ¶ 6). In fact, Stephens expressly teaches that the catheter 202 is inserted into the position guide 100 by pressing the catheter 202 through the open channel 104. (Stephens at col. 2, lines 45-49, col. 3, lines 25-28). There is no disclosure in Stephens of inserting the catheter 202 through the proximal end of the position guide 100 as is done with the claimed introducer.

There also would have been no motivation to modify Figures 1-8 of Applicants' specification to achieve the claimed invention. The prior art of record fails to disclose an introducer made of a flexible plastic sheath with a longitudinal slot and a beveled distal end or a flanged proximal end. In order function properly, an introducer must be designed to force open the valve member of a hemastatic valve. (Schaeffer ¶ 7). This requires substantial column and circumferential strength to overcome the pressure imposed by the valve member. (Schaeffer ¶ 7). The Stephens position guide 100 did not confront this problem because Stephens discloses using a Tuohy-Borst connector 308 and not the hemastatic valve of the application. (Schaeffer ¶ 7). Indeed, Figures 1-8 of the present application teach away from adding a longitudinal slot to a flexible plastic sheath for an introducer because the only prior art introducer which had a slot was made from rigid metal. (Schaeffer ¶ 7). Thus, one of ordinary skill in the art would have been led away from the claimed invention because it was believed that rigid metal was needed with a slotted introducer to overcome the column pressure and circumferential pressure of a hemastatic valve. (Schaeffer ¶ 7).

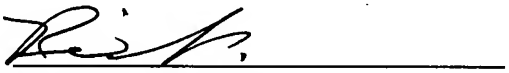
Mr. Schaeffer is fully qualified to be considered one of ordinary skill in the art. (Schaeffer ¶ 1, 4). His understanding of the prior art and the motivations of those of ordinary skill in the art deserve to be given due weight in evaluating whether the claimed invention is patentable over the prior art.

Because the prior art of record does not disclose or suggest all of the limitations of claims 1, 21 and 22, Applicants' independent claims are allowable as now presented. Claims 2-20 and 24-41 are also allowable since these claims depend from claims 1 and 22. Any further arguments that could be made in support of Applicants' dependant claims would be superfluous and are unnecessary at this time.

Conclusion

In response to the Examiner's comments, Applicants have amended claims 1, 3, 12, 14, 17, 19-22, 33 and 38 and have cancelled claim 23. None of the prior art of record discloses or suggests all of the limitations required by the claims as now presented. In particular, none of the prior art of record discloses or suggests an introducer for medical devices made from a flexible sheath with a longitudinal slot and a beveled distal end or a flanged proximal end. Thus, Applicants' claims are allowable. Accordingly, Applicants request reconsideration and allowance of the application.

Respectfully submitted,



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